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ORIGINAL ARTICLE

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Primary stabilizing effect of interbody fusion devices for the cervical spine: an in vitro comparison between three different cage types and bone cement

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Abstract Interbody fusion cages are small hollow implants that are inserted into the intervertebral space to restore physiological disc height and to allow bony fusion. They sometimes cause clinical complications due to instability, subsidence or dislocation. These are basic biomechanical parameters, which influence strongly the quality of a fusion device; however, only few data about these parameters are available. Therefore, the purpose of the present study was to investigate the primary stabilizing effect of four different cervical fusion devices in in vitro flexibility tests. Twenty-four human cervical spine segments were used in this study. After anterior discectomy, fusion was performed either with a WING cage (Medinorm AG, Germany), a BAK/C cage (Sulzer SpineTech, USA), an AcroMed cervical I/F cage (DePuy AcroMed International, UK) or bone cement (Sulzer, Switzerland). All specimens were tested in a spine tester in the intact condition and after implantation of one of the four devices. Alternating sequences of pure lateral bending, flexion-extension and axial rotation moments (± 2.5 Nm) were applied continuously and the motions in each segment were measured simultaneously. In general, all tested implants had a stabilizing effect. This was most obvious in lateral bending, where the range of motion was between 0.29 (AcroMed cage) and 0.62 (BAK/C cage) with respect to the intact specimen (= 1.00). In lateral bending, flexion and axial rotation, the AcroMed cervical I/F cages had the highest stabilizing effect, followed by bone cement, WING cages and BAK/C cages. In extension, specimens fused with bone cement were most stable. With respect to the primary stabilizing effect, cages, especially the AcroMed I/F cage but also the WING cage and to a minor extent the BAK/C cage, seem to be a good alternative to bone cement in cervical interbody fusion. Other characteristics, such as the effect of implant design on subsidence tendency and the promotion of bone ingrowth, have to be determined in further studies.

Key words Cervical spine · Biomechanics · Flexibility · Interbody fusion device

Introduction

Many different surgical treatments for degenerative diseases of cervical intervertebral discs exist. One of them is anterior cervical interbody fusion. A discectomy is carried out from an anterior approach and a spacer is implanted into the intervertebral space. Bone graft [6, 28] or bone cement [8, 25] are counted among these intervertebral spacers. However, complications like graft expulsion, non-union or bone graft collapse have been reported [5, 7, 14, 15, 31].

In order to minimize the complication rates, an attempt was made to implant resorbable polymers or ceramics [14], but the success of these implants is not yet satisfactory.

Therefore, interbody fusion cages have been developed. They are small hollow implants that restore physiological disc height and stabilize spinal segments, primarily in distracting them [2] and secondarily in allowing through-the-implant growth of bone and bony fusion. To allow bone ingrowth, most cages have a central cavity to be filled with autologous cancellous bone [3, 4, 13, 16, 18], sterilized allograft bone [3] or other osteoinductive material [17, 35] and lateral, upper and lower windows or pores. But some of these cages can cause clinical complications due to instability, subsidence or dislocation [1, 11, 24]. These are basic biomechanical characteristics, which influence strongly the quality of a fusion device; however, only few data about these parameters are available.

The aim of the present study was to investigate the primary stabilizing effect of four different fusion devices for the cervical spine, including the new WING cage, two already established cages (BAK/C and AcroMed cervical I/F) and bone cement, in in vitro flexibility tests. This may provide an important part of the database needed for prediction of the clinical outcome of cervical fusion devices.

Materials and methods

Devices

The four cervical interbody fusion devices tested in the present study were: the new WING cage (Medinorm AG, Quierschied/Saar, Germany), the BAK/C cage (Sulzer Spine-Tech, Minneapolis, USA), the AcroMed cervical I/F cage (DePuy AcroMed International, Leeds, UK) and bone cement (Duracem, Sulzer Medica, Winterthur, Switzerland) (Fig. 1). All three cages as well as the bone cement have to be implanted from an anterior approach under distraction of the affected segment.

The WING cage is a titanium-alloy implant, composed of a cylindrical middle part and two lateral wings (Fig. 1 A). Large holes allow a through-the-implant growth of bone. Before implantation, a groove has to be drilled, in an anterior-posterior direction, in both adjacent endplates. The cage then has to be stuck into the intervertebral space. As a result of the drilling, the middle part is in contact with cancellous bone; however, the lateral wings are in contact with intact parts of the endplates.

The BAK/C cage is a threaded, hollow titanium-alloy cylinder (Fig. 1 B). Several pores allow for bone ingrowth. It is screwed into the prepared bone bed either in pairs bilaterally (implants with a 6 or 8 mm diameter) or singly centrally (10 or 12 mm). In this study, only the single centrally placed 10- and 12-mm implants were used in order to improve the comparability of the results.

The AcroMed cervical I/F cage is made from carbon fibers embedded in a polymer matrix (PEEK, polyetheretherketone). It has a trapezoidal, slightly wedged shape and a hollow inner space that assists bony fusion (Fig. 1 C). AcroMed-cages are stuck into the intervertebral space.

Bone cement is an autopolymerizing methacrylate derivate (Fig. 1 D). A lodging for the cement has to be created by drilling a hole into the midportion of both adjacent vertebral bodies. The posterior aspect of the disc space has to be coated with gelatin before pouring the methyl methacrylate in a semiliquid consistency into the intervertebral space. Cervical interbody fusion with bone cement is assumed to have a good primary stabilizing effect and is an accepted operative procedure [8, 22, 25]. Therefore, it will serve as a baseline for comparison with the three cages.

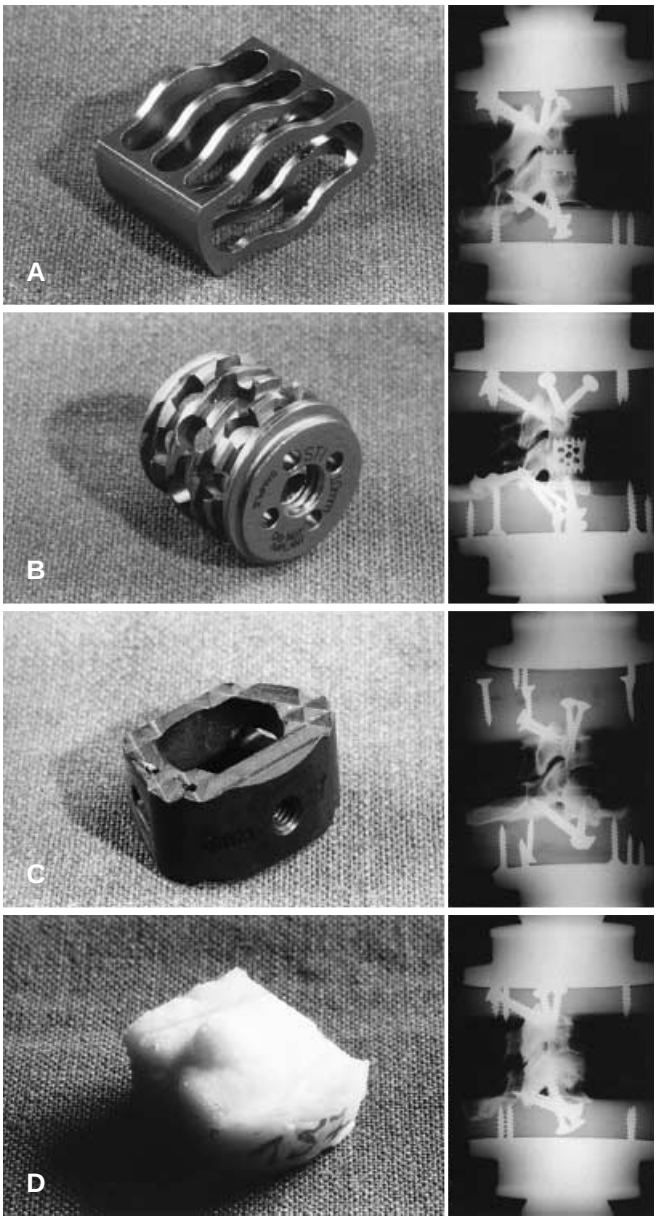

Fig. 1 A–D Photographs (*left*) and plain lateral radiographs (*right*) of the three anterior cervical fusion cages and bone cement. **A** WING cage (Medinorm AG, Quierschied/Saar, Germany), **B** BAK/C cage (Spinetech, Minneapolis, USA), **C** AcroMed I/F cage (DePuy AcroMed International, Leeds, UK), and **D** bone cement dowel, explanted after testing (Duracem, Sulzer Medica, Winterthur, Switzerland)

Table 1 Characteristics of 24 human cervical spine specimens (8 × C2–3, 8 × C4–5, 8 × C6–7) divided into four groups (n = 6), one group for each of the four devices. Bone mineral density, age and sex distribution across the four groups were nearly equal. Mean values and standard deviations are presented (*BMD* bone mineral density in mg/ccm hydroxylapatite equivalent)

	Group 1 WING	Group 2 BAK/C	Group 3 AcroMed I/F	Group 4 Bone cement
No. of segments				
C2–3	2	2	2	2
C4–5	2	2	2	2
C6–7	2	2	2	2
BMD in mg/ccm	202.3 ± 49.7	206.0 ± 44.8	195.0 ± 53.1	216.9 ± 61.8
Age (years)	58.8 ± 7.1	58.7 ± 7.4	58.5 ± 4.3	61.8 ± 5.6
Sex distribution m : f	4 : 2	3 : 3	4 : 2	3 : 3

Specimens

Twenty-four segments from ten cervical human spines (eight C2–3, eight C4–5 and eight C6–7) were used in this study. Even though C2–3 is rarely affected by degenerative disc diseases, this segment was included in the study as it shows similar biomechanical characteristics [20, 32] and anatomical dimensions of the lower endplate [9, 19, 30] compared to the lower cervical spine. All specimens were freshly dissected and frozen at –20°C until testing. Their bone mineral density was measured using quantitative computed tomography (Stratec XCT 960, Pforzheim, Germany). They were then divided into four equal groups with respect to bone mineral density, age and sex (Table 1).

Specimen preparation

Before testing, the specimens were thawed at room temperature. All muscles were then carefully removed, taking care to ensure the preservation of the discs, ligaments and facet joint capsules. For each of the specimens, the upper half of the upper vertebra and the lower half of the lower vertebra were embedded in polymethyl methacrylate (PMMA, Technovit 3040, Heraeus Kulzer GmbH, Wehrheim/Ts, Germany). Before embedding, several screws were inserted into both vertebrae in order to improve the fixation between vertebra and PMMA.

In all specimens, an anterior discectomy with resection of the anterior as well as the posterior longitudinal ligament was performed. Resection of the posterior longitudinal ligament was carried out because this often becomes necessary in patients with posterior nucleus prolapse or with posteriorly growing osteophytes. Care was taken to preserve the lateral parts of the annulus. The devices were then implanted from an anterior direction using tools designed by the cage manufacturers and following their recommended protocols. Cage sizes were chosen to correspond with the specimen sizes. During implantation of WING cages, AcroMed cages and bone cement, a distraction was carried out with a Caspar distractor (Aesculap AG, Tuttlingen, Germany). During implantation of the BAK/C cages, distraction was achieved with special distraction instruments designed by the cage manufacturer.

After implantation, plain posterior-anterior and lateral radiographs were taken in order to document the position of the implants (Fig. 1).

Flexibility test

Each specimen was tested in the intact condition and after implantation of one of the four devices. For this purpose, they were fixed in a spine tester [33] (Fig. 2). Alternating sequences of right/left lateral bending (±Mx), flexion/extension (±My), and left/right axial rotation (±Mz) moments were applied continuously at a constant rate of 1.0°/s by stepper motors integrated into the gimbal of the spine tester. Two precycles were applied to minimize the effect of the viscous component in the viscoelastic response, and data were collected on the third. The specimens were tested without axial preload under loads of between +2.5 Nm and –2.5 Nm, starting and ending in neutral position with zero load. These moments were chosen to stay within the viscoelastic range of the specimens [34]. The

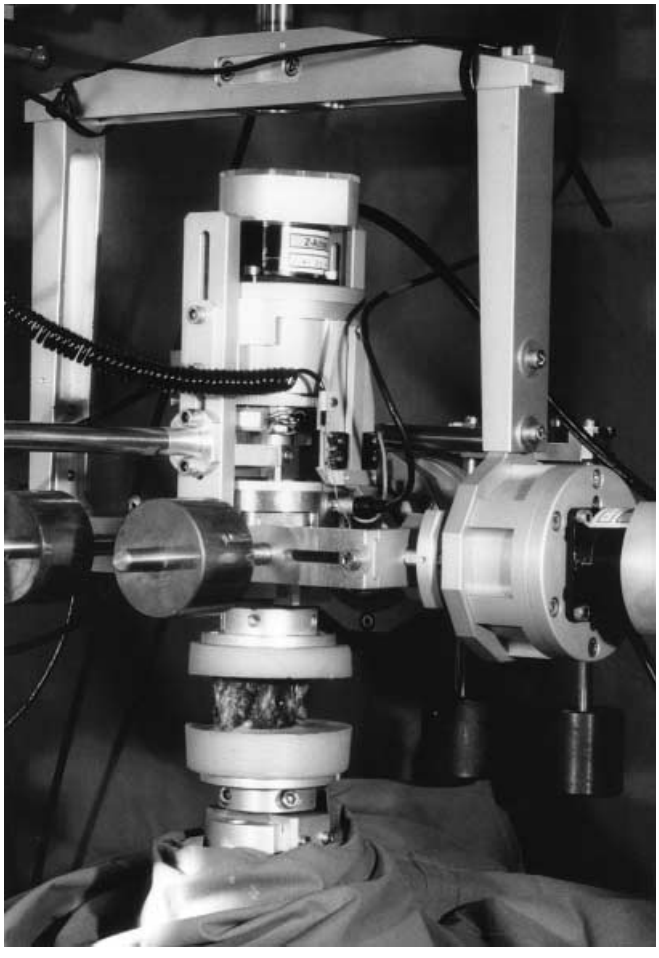

Fig. 2 Spine tester with a C4–5 specimen mounted. The specimens were loaded with pure moments (±2.5 Nm) applied by stepper motors integrated into the gimbal of the spine tester. The six motion components in each segment were recorded simultaneously by rotary variable displacement transducers within the three axes of the cardan joint

motion in each single segment was measured simultaneously using three rotary variable displacement transducers (RVDT) (Novotech, Ostfildern, Germany) integrated into the three axes of the gimbal.

Measurement of distraction height and angulation due to distraction

With respect to the primary stabilizing effect of interbody implants, the distraction force seems to play an important role. Exact measurements of this parameter, however, are technically problematic. Distraction height, which represents an indirect sign of the force applied to distract the specimen, is much easier to determine. Distraction height was measured in a strictly upright position of the specimen, with a displacement transducer (linear variable differential transformer, TransTek 87244-000, Burster, Gernsbach, Germany) integrated into the axial translation axis of the spine tester. The specimens were then allowed to relax completely. In this relaxed position, the angulation of the upper vertebra with respect to the lower one was measured by the above mentioned RVDT's. Since only 12 specimens (3 of the WING group, 3 of the BAK/C group, 2 specimens of AcroMed group, 4 specimens of the cement group) could be strightened up with loads up to ± 2.0 Nm only sample measurements were taken of the distraction height and angulation due to distraction.

Data analysis and statistics

Range of motion (ROM) and neutral zone (NZ) were determined from the resulting load-deformation curves (Fig. 3). ROM was defined as the angulation at the maximum moment for the two directions separately. NZ is a measurement of the laxity of the spinal specimen. It was defined as the difference in angulation at zero load between two phases of motion.

For normalization, ROM and NZ after implantation of one of the four devices were divided by the ROM of the intact specimen.

The distribution of the single values has to be assumed to be non-parametric. Therefore, in a first step, median, minimum and maximum values of the normalized ROM and NZ were calculated for each device group separately. In a second step, paired comparisons between the four device groups were carried out using the Mann-Whitney U-test. A correction for multiple comparisons was not carried out, because all *P*-values would have exceeded the level of significance. Therefore, the *P*-values listed in this paper are considered to indicate tendencies and to underline the descriptive statistics, and are not considered to reveal statistically significant differences.

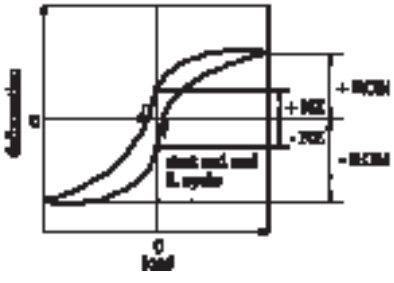

Fig. 3 Typical load-displacement curve (cycle 3) under continuously changing load. Illustration of the parameters (range of motion, ROM; neutral zone, NZ). Positive load indicates right lateral bending (+M*x*), or flexion (+M*y*) or left axial rotation (+Mz), and negative load indicates left lateral bending (–M*x*), or extension (–M*y*) or right axial rotation (–Mz)

Results

All tested cervical interbody fusion devices had a stabilizing effect on the specimens in which they were implanted (Figs. 4–6). The only exception was the BAK/C cages, which had a slightly destabilizing effect in extension. In lateral bending, flexion and axial rotation, the AcroMed cervical I/F cages had the highest stabilizing effect, followed by bone cement, WING cages and BAK/C cages. In extension, specimens fused with bone cement were most stable.

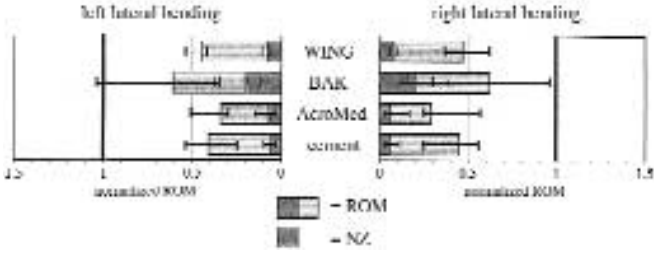

Fig. 4 Normalized ROM (*dark gray plus light gray*) and NZ (*dark gray only*) in right and left lateral bending after fusion with WING, BAK/C, AcroMed I/F cages or bone cement. A value lower than 1.0 describes a stabilizing effect and a value higher than 1.0, a destabilizing effect. Median and range values are presented

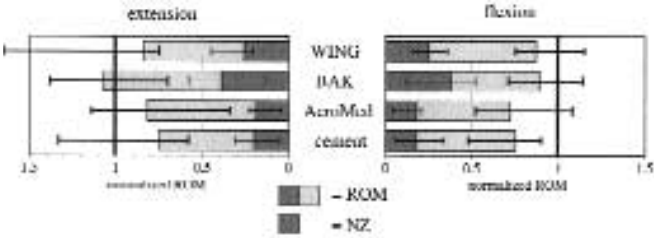

Fig. 5 Normalized ROM (*dark gray plus light gray*) and NZ (*dark gray only*) in flexion and extension after fusion with WING, BAK/C, AcroMed I/F cages or bone cement. A value lower than 1.0 describes a stabilizing effect and a value higher than 1.0, a destabilizing effect. Median and range values are presented

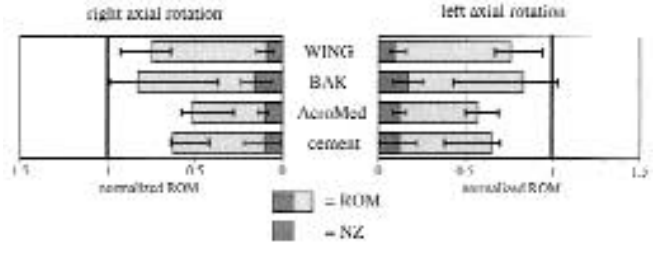

Fig. 6 Normalized ROM (*dark gray plus light gray*) and NZ (*dark gray only*) in left and right axial rotation after fusion with WING, BAK/C, AcroMed I/F cages or bone cement. A value lower than 1.0 describes a stabilizing effect, a value higher than 1.0, a destabilizing effect. Median and range values are presented

Table 2 *P*-values for paired comparisons (Mann-Whitney U-test) between the normalized range of motion (ROM) of specimens treated with WING cages, BAK/C cages, AcroMed I/F cages or bone cement. All *P*-values are considered to show tendencies and not statistical evidence, because correction for multiple was not carried out

	Right lateral bending	Left lateral bending	Flexion	Extension	Left axial rotation	Right axial rotation
WING vs BAK	0.1495	0.2980	> 0.9999	0.2623	0.8102	0.4712
WING vs AcroMed	0.0782	0.0250	0.0656	0.5218	0.0065	0.0039
WING vs cement	0.7488	0.3367	0.0927	0.2623	0.0547	0.1735
BAK vs AcroMed	0.0250	0.0250	0.0782	0.1495	0.0782	0.0374
BAK vs cement	0.0782	0.1093	0.0547	0.1495	0.1093	0.2002
AcroMed vs cement	0.3785	0.4233	> 0.9999	0.8102	0.5752	0.1495

All four fusion devices had the best stabilizing effect in lateral bending. In this loading direction, the range of motion (ROM) after implantation was between 0.29 (AcroMed cage) and 0.62 (BAK/C cage) relative to the ROM before implantation (= 1.00). Next best stabilization was achieved in axial rotation (0.52–0.83), followed by flexion (0.72–0.89) and extension (0.82–1.07).

In lateral bending, the AcroMed cage group showed the best median normalized ROM of 0.29 (lateral bending to the right) and 0.34 (lateral bending to the left), followed by the bone cement group (0.45 and 0.41), the WING group (0.47 and 0.45) and the BAK/C group (0.62 and 0.61) (Fig. 4). In the Mann-Whitney U-test for paired comparisons, lowest *P*-values were found for the differences between BAK/C and AcroMed I/F ($P = 0.0250$ in both directions) and between WING and AcroMed I/F ($P = 0.0782$ in right lateral bending and $P = 0.0250$ in left lateral bending) (Table 2). NZ in lateral bending was smallest in the bone cement group (0.06 and 0.06) and largest in the BAK/C group (0.20 and 0.20).

In flexion, the median ROMs of the four device groups were similar, and ranged from 0.72 in the AcroMed group to 0.89 in the BAK/C group (Fig. 5). Median NZ in flexion was similar in the AcroMed and in the bone cement group (0.18), slightly higher in the WING group (0.25) and largest in the BAK/C group (0.38).

In extension, bone cement, AcroMed I/F and WING cages had a slightly stabilizing effect (normalized ROM of 0.75, 0.82 and 0.84), while the BAK/C cages had a *destabilizing* effect (1.07) with respect to the intact condition (Fig. 5). Median NZ in extension was similar in the AcroMed and the bone cement groups (0.19 and 0.20 respectively), slightly higher in the WING group (0.26) and highest in the BAK/C group (0.39).

In axial rotation, all three device groups showed values higher than 0.5. The AcroMed cage group had the highest stabilizing effect, with 0.57 (axial rotation to the left) and 0.52 (axial rotation to the right). A slightly higher ROM was noted in the bone cement group (0.65 and 0.63). The largest values were found in the WING group (0.76 and 0.75) and in the BAK/C group (0.83 and 0.83) (Fig. 6). In the Mann-Whitney U-test for paired comparisons, the lowest *P*-values were found between WING and AcroMed I/F ($P = 0.0065$ in left axial rotation and $P = 0.0039$ in right axial rotation) and between BAK/C and AcroMed I/F ($P = 0.0782$ and $P = 0.0374$) (Table 2). The median NZ in axial rotation was nearly equal across the WING, the AcroMed and the cement groups (0.09, 0.12 and 0.12 respectively in axial rotation to the left, and 0.09, 0.10 and 0.10 in axial rotation to the right) and slightly higher in the BAK/C group (0.17 and 0.16).

The values for the sample measurements of distraction height ranged from 1.4 to 2.1 mm in the WING group, 1.1 to 1.8 mm in the BAK/C group, 1.8 to 2.5 mm in the AcroMed group and 1.1 to 2.4 mm in the cement group. After implantation, a lordotic angulation could be observed in most specimens. However, it varied strongly and was found to be up to 10° in the AcroMed group, but smaller in the WING and the cement group. In the BAK/C group, even slight kyphotic angulations of up to 1.2° could be observed.

Discussion

In the present study, the primary stabilizing effect of four different fusion devices for the cervical spine, including the new WING cage, two already established cages (BAK/C and AcroMed cervical I/F) and bone cement was investigated in in vitro flexibility tests.

In general, all tested implants had a stabilizing effect (Figs. 4–6). This finding refers to the distraction-compression principle [2]. Intraoperative distraction leads to a tightening of the annulus fibers that had been preserved during implantation. This tightening causes a compression of the interbody implant, which improves its fixation and increases stability.

All tested fusion devices had the best stabilizing effect in lateral bending, followed by axial rotation, flexion and extension (Fig. 4, Fig. 5, Fig. 6). During anterior cervical interbody fusion, the anterior, medial and posterior parts of the intervertebral discs are removed, while the lateral parts of the annulus are preserved. These lateral parts still possess a stabilizing potential against lateral bending moments. In extension, the absence of the anterior part of the annulus reduces the resistance against extension stress. However, excessive extension was observed because the spinous prosesses of the adjacent vertebrae touched each

other especially in specimens where implantation caused a lordotic angulation.

In lateral bending, flexion and axial rotation, the AcroMed I/F cage had the largest stabilizing effect, followed by bone cement, the WING cage and the BAK/C cage (Fig. 4, Fig. 5, Fig. 6). This finding can partially be explained by the different shapes of the four devices. With its trapezoidal shape, the AcroMed I/F cage matches the natural anatomical dimensions of the endplates better than the other cages. Moreover, its lateral flanks are in contact with the uncinate process, and therefore strongly constrain axial rotation movements. The lateral wings of the WING cage, which support the endplates, increase primary stability especially in lateral bending. On the other hand, in this loading direction, the cylindrical shape of the BAK/C cage allows large movements, because both adjacent vertebrae may roll on the cylindrical centrally placed cage. This effect would not be expected if two cages were placed bilaterally, as recommended for 6- and 8-mm implants. Bone cement shows the best primary fit; however, it stabilizes slightly less effectively than the AcroMed cage.

Therefore, other parameters, besides the implant shape, seem to influence the primary stabilizing effect of interbody fusion devices. One of these parameters is the distraction force. It determines the amount of the compression that fixates the interbody implant and produces stability. As the distraction force is technically hard to measure, sample measurements were taken of the the distraction height as an indirect sign of the force in 12 specimens. It varied strongly, and was between 1.1 and 2.5 mm. No distinct differences between the four device groups were revealed. However, the distraction height seemed to be slightly smaller with BAK/C cages (max 1.8 mm) than with WING cages (max 2.1 mm), AcroMed cages (maximum 2.5 mm) or bone cement (max 2.4 mm). Therefore, distraction with the Caspar distractor, which was used for implantation of WING cages, AcroMed cages and bone cement, seems to be more powerful than distraction with the specially designed distraction pin used for BAK/C cages. One can conclude that, with BAK cages, both the cylindrical shape as well as the smaller distraction height may be responsible for the lower primary stabilizing effect.

The level of stability that is necessary for bony fusion is not yet known. Therefore, interpretation of the absolute ROM is difficult, and predictions about the clinical fusion rate should only be carried out cautiously. Furthermore, in vitro stability tests only reflect the acute postoperative stability; biological effects can not be predicted, though they do play an important role. All loading parameters were chosen following the recommendations of the German Society for Spinal Surgery [34]. However, it should be borne in mind that, in vivo, the cervical spine is loaded by an axial preload, which may provoke subsidence and therefore influence stability.

However, the comparison with a fusion device that is known to have a sufficient primary stabilizing effect, such as bone cement, represents an important baseline, which might make clinical interpretation possible.

Only a few reports of in vitro tests of cervical interbody fusion cages are available in the literature for comparison [27, 29]. However, several in vitro stability tests with lumbar interbody fusion cages have already been published. In general, the design of a lumbar cage seems to have no significant influence on its stabilizing potential [13] and its biomechanical characteristics [23]. Furthermore, posterior lumbar cages generally decrease the intervertebral movement lateral bending and in flexion, but increase it in axial rotation and extension [13, 18].

In contrast to in vitro tests, several clinical follow-ups have been carried out with patients who were treated with cervical interbody fusion cages. Anterior interbody fusion with BAK/C cages in cervical spondylosis revealed a bone fusion rate of 90% after 6 months and 100% after 12 months [16]. Except for one case, there were no signs of instability, cage migration, kyphosis or pseudarthrosis. In another clinical trial, a bone fusion rate of 100% was found 18 months after implantation of AcroMed cervical I/F cages [4]. These two follow-ups reveal higher fusion rates than those reported with lumbar cages, where fusion rates of 91% (lumbar BAK cages) [11] and 96% (lumbar Ray cages) [24], 2 years after operation, were found. But as the fusion rate is difficult to determine in vivo, these results have to be interpreted cautiously. Both reports of cervical cage trials [4, 16] deal with preliminary results; long-term results have not yet been reported. However, experience suggests long-term complications in the use of cervical cages, such as subsidence of the cages into the adjacent vertebrae or bone resorption within the cages [7, 10, 12, 15]. Bone resorption and substitution by soft tissue may be caused by insufficient stability [21] or by inadequate loading of the bone within the cages. In order to avoid such stress protection, the new WING cage design allows vertical loading of the bone inside the cage. The contact area between cage and vertebra is assumed to remain large enough to inhibit excessive subsidence.

Conclusion

Although we do not yet know at which level of ROM bony ingrowth is inhibited, we can assume the smaller the better. With respect to the primary stabilizing effect, cages – especially the AcroMed I/F cage but also the WING cage and to a minor extent the BAK/C cage – seem to be an alternative to bone cement in cervical interbody fusion.

With geometrical optimization, those cages – particularly the WING and the Acromed – in contrast to bone cement, may allow bony ingrowth and reduction of stress protection inside the cage.

However, the design also has to prevent subsidence into the adjacent vertebrae. These characteristics have to be investigated in further studies.

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